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K040413
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510(k) Summary of Safety and Effectiveness

Submitter

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Oosteinde 8
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The Netherlands

FDA Establishment Registration Number 9610978

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Date June 11, 2004
Prepared:

Device Name and Classification

Trade Name:	Cordis Palmaz® BLUE™ .018 Transhepatic Biliary Stent System
Common Name:	Biliary Stent (incl. Accessories)
Classification Name:	21 CFR 876.5010 - Biliary Catheter
Device Classification:	Class II
FDA Classification Panel:	Gastro-enterology
Product Code:	FGE

00097

Performance Standards / Special Controls

There are no performance standards applicable under section 514 of the Food, Drug, and Cosmetic Act for this device.

The contents of this 510(k) premarket notification have been prepared based upon the FDA's – Guidance for the content of premarket notifications for metal expandable biliary stents. February 5, 1998

Intended Use

The Cordis Palmaz BLUE .018 Transhepatic Biliary Stent System is indicated for the palliation of malignant neoplasms in the biliary tree.

Product Description

The PALMAZ BLUE Transhepatic Biliary Stent is a balloon expandable Cobalt Chromium Biliary stent. The stent is provided premounted on a balloon catheter, i.e., the Cordis SLALOM 0.18" Delivery System. The stent and delivery system are advanced over a guidewire through a sheath lumen, via the use of a stainless steel introducer tube accessory, (which is provided together with the Palmaz BLUE .018 Transhepatic Biliary Stent System) to an obstruction site in the biliary tree where the balloon is then inflated to expand the stent. After full expansion of the stent, the balloon is then deflated and subsequently the delivery system is removed. The Cordis PALMAZ BLUE .018 Transhepatic Biliary Stent System is provided sterile (via Ethylene Oxide sterilization) and is intended for single use only.

Summary of Studies

The safety and effectiveness of the device and the substantial equivalence to the predicate devices have been demonstrated via data collected from non-clinical in-vitro and animal testing (stent placement in biliary duct) which was prescribed in the FDA's – Guidance for the content of premarket notifications for metal expandable biliary stents. February 5, 1998. The Cobalt Chromium based stent material has been tested according to the ISO10993 part 1 and were concluded biocompatible.

Summary of Substantial Equivalency

The intended use, components, dimensions (size range), accessories, method of delivery, fundamental technology (operating principle), packaging configuration and packaging materials, manufacturing and sterilization processes featured with the Cordis Palmaz BLUE .018 Transhepatic Biliary Stent System are substantially equivalent to those featured with the predecessor Cordis PALMAZ GENESIS Transhepatic Biliary Stent on SLALOM .018" Delivery System. With respect to the stent material (Cobalt Chromium-alloy), substantial equivalence is claimed to the De Puy Anatomic Modular Knee (AMK) Posterior Stabilized

Predicate Devices

The following table provides information on the predicate devices.

Device	Company	510k #	Concur Date	Substantial Equivalence
PALMAZ GENESIS Transhepatic Biliary Stent on SLALOM .018" Delivery System	Cordis Europa, N.V. (part of Cordis Corporation)	K021345	28 Jun 2002	Same intended use Same stent delivery system Same operating principle Same stent dimensions (diameters & lengths)
PALMAZ GENESIS Transhepatic Biliary Stent on SLALOM .018" Delivery System	Cordis Europa, N.V. (part of Cordis Corporation)	K012056	1 Aug 2001	Same accessory Same shelf life Same packaging materials Same manufacturing processes Same sterilization process Same sterilization assurance level of 10 ⁻⁶
Anatomic Modular Knee (AMK) Posterior stabilized	De Puy Inc. (a Johnson & Johnson company)	K901406	23 July 1990	Same material, i.e. (L605) Cobalt-Chromium-alloy (conform ASTM F90) used for stabilizing post of the knee system (implant)
Anatomic Modular Knee (AMK) Landmark Revision Knee	De Puy Inc. (a Johnson & Johnson company)	K925072	21 Jan 1994	
Anatomic Modular Knee (AMK) Posterior Stabilized	De Puy Inc. (a Johnson & Johnson company)	K933304	30 August 1993	



Food and Drug Administration
9200 Corporate Boulevard
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Albert Roossien, Ph.D.
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THE NETHERLANDS

Re: K040413
Trade/Device Name: Cordis Palmaz® BLUE™ .018 Transhepatic Biliary Stent System
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: June 11, 2004
Received: June 14, 2004

Dear Dr. Roossien:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Page 2 – Albert Roossien, Ph.D.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K040413

Device Name: Cordis Palmaz® BLUE™ .018 Transhepatic Biliary Stent System

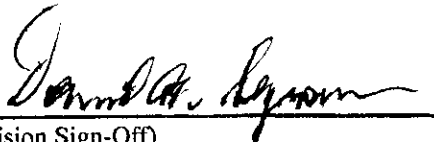
FDA's Statement of the Indications For Use for device:

The Cordis Palmaz® BLUE™ .018 Transhepatic Biliary Stent System is indicated for the palliation of malignant neoplasms in the biliary tree.

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-the-Counter Use ☐



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K040413